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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/859,439	05/18/2001	Indra Prakash	2047.154	3715

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EXAMINER

ZUCKER, PAUL A

ART UNIT	PAPER NUMBER
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1623

DATE MAILED: 12/17/2001

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Please find below and/or attached an Office communication concerning this application or proceeding.

**Office Action Summary**

Application No.

09/859,439

Applicant(s)

PRAKASH, INDRA

Examiner

Paul A. Zucker

Art Unit

1623

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☐ Responsive to communication(s) filed on \_\_\_\_.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-20 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1,2,4-10,12,14 and 16-20 is/are rejected.
- 7) ☒ Claim(s) 13 and 15 is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on \_\_\_\_ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

**Priority under 35 U.S.C. §§ 119 and 120**

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

**Attachment(s)**

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) \_\_\_\_.
- 4) ☐ Interview Summary (PTO-413) Paper No(s). \_\_\_\_.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: \_\_\_\_\_.

## DETAILED ACTION

### *Specification*

1. The disclosure is objected to because of the following informalities:
  - a. Page 8, line 5 The phrase "toluenesulfonate" is a name fragment;
  - b. Page 8, lines 9-10 The phrase "toluene sulfonic" should be one word;
  - c. Page 12, lines 14+ Text missing?
  - d. Page 16, line 7 The phrase "toluene sulfonic" should be one word. This and all other occurrences should be corrected.

Appropriate correction is required.

2. The abstract is objected to. It does not clearly present the invention's contribution to the art. Applicant is reminded of the proper content of an Abstract of the Disclosure. In chemical patent abstracts for compounds or compositions, the general nature of the compound or composition should be given as well as its use, e.g., "The compounds are of the class of alkyl benzene sulfonyl ureas, useful as oral anti-diabetics." Exemplification of a species could be illustrative of members of the class. For processes, the type reaction, reagents and process conditions should be stated, generally illustrated by a single example unless variations are necessary. Complete revision of the content of the abstract is required on a separate sheet.

***Claim Objections***

3. Claims 13 and 15 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

***Claim Rejections - 35 USC § 112***

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

4. Claim 1 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Claim 1 recites the limitation "sufficient to produce" in lines 7 and 13. It is unclear whether Applicant intends that the indicated reaction be completed or only initiated within the specified limits. This renders the scope of the claim unclear and therefore the claim indefinite.
5. Claim 3 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Claim 3 recites the limitation "activated carbonyl compound" in line 2. Dimethyl or diethyl acetals are not properly characterized as "activated" carbonyl compounds but rather as "masked" carbonyl compounds. This renders the claim indefinite.
6. Claim 11 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Claim 3 recites the limitation "p-toluenesulfonate" in line 2.

This is a fragment of a compound name and thus renders the scope of the claim unclear and the claim indefinite.

7. Claims 6-9 and 17-20 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. These claims each recite the limitation "sufficient to produce" in line 2. It is unclear whether Applicant intends that the indicated reaction be completed or only initiated within the specified limits. This renders the scope of the claims unclear and therefore the claims indefinite.

### ***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

8. Claims 1, 2, 4-10, 12, 14 and 16-20 are rejected under 35 U.S.C. 103(a) as being unpatentable over Burger et al (Chemmiker Zeitlung 1990, 114(7-8), pages 249-251) and further in view of Claude et al (US 5,510,508 04-1996). Burger discloses (Page 250, left column, lines 17-34) the synthesis of oxazolidinones of general structure 3 (Page 249, upper right-hand column) which, with  $n=1$  (compound 3a), corresponds to that derived from aspartic acid. The amino acid (100 mmol) in anhydrous dimethylsulfoxide is vigorously stirred at room temperature and a gaseous stream of hexafluoroacetone is introduced. The introduction of hexafluoroacetone is stopped

Art Unit: 1623

when its uptake ceases and reflux is noted. Thus while Burger is silent with respect to the reactant ratios it reasonable to assume the instant claimed slight excess (1:1.1-1.4) of hexafluoroacetone. Reaction is continued for 2-3 hours to give the crystalline oxazolidinone after work-up. The Examiner notes that aspartic acid itself meets the limitation of an acid which serve as a catalyst to produce hexafluoroacetone hydrate. Burger further discloses (Page 250, last 5 lines of left column- first 9 lines of right column) the aminolysis of the oxazolidinones to form dipeptides such as aspartame. The oxazolidinone (20 mmol) in anhydrous ether is slowly added with stirring at room temperature to a solution of phenylalanine methyl ester (24 mmol) in anhydrous ether (corresponding to 1:1.2 ratio of oxazolidinone:phenylalanine) and reaction continued for 24 hr to give a 72% yield of aspartame. Burger is silent with respect to use of his process for the synthesis of N-[N-(3,3-dimethylbutyl)-L- $\alpha$ -aspartyl-L-phenylalanine-1-methyl ester (neotame). Claude, however, discloses (Column 1, lines 1-42) the structure of neotame an artificial sweetener closely related in structure to aspartame. The closeness of the relationship between these two compounds is underscored by the fact that Claude further discloses (Column 3, line 63 – column 4, line 40) the synthesis of neotame in one step from aspartame. Thus it would have been obvious for one of ordinary skill in the art to have performed the instant invention at the time Applicant asserts it was made. The motivation would have been to apply the efficient process disclosed by Berger for the synthesis of aspartame, a commercially important artificial sweetener, to the synthesis of the aspartame derivative, neotame. The expectation for success

Art Unit: 1623

would be exceptionally strong because of the close structural similarities between aspartame and neotame.

***Allowable Subject Matter***

9. Claims 3, 11,13 and 15 are drawn to allowable subject matter. The following is a statement of reasons for the indication of allowable subject matter: The closest art of record, Burger et al (Chemmiker Zeitlung 1990, 114(7-8), pages 249-251) neither discloses nor fairly suggests the limitations of claims 3, 11,13, 15. No suggestion exists that acetals in the presence of pyridinium p-toluenesulfonate or p-toluenesulfonic acid can substitute for hexafluoracetone or that the oxazolidinone formation and aminolysis can be carried out in the same solvent.

***Conclusion***

10. Claims 1-20 are outstanding. Claims 1, 2, 4-10, 12, 14 and 16-20 are rejected. Claims 13 and 15 are objected to.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Paul A. Zucker whose telephone number is 703-306-0512. The examiner can normally be reached on Monday-Friday 7:00-3:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Geist can be reached on 703-308-1701. The fax phone numbers for the organization where this application or proceeding is assigned are 703-308-4556 for regular communications and 703-308-4556 for After Final communications.

Art Unit: 1623

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-1235.

PAZ  
December 10, 2001



GARY GEIST  
SUPERVISORY PATENT EXAMINER  
TECH CENTER 1600